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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,018	01/15/2002	Eduardo N. Mitrani	01/22527	8957
7590 03/19/2004				
c/o ANTHONY CASTORINA G.E. EHRLICH (1995) LTD. SUITE 207 2001 JEFFERSON DAVIS HIGHWAY ARLINGTON, VA 22202			EXAMINER TON, THAIAN N	
			ART UNIT 1632	PAPER NUMBER

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/045,018

Applicant(s)

MITRANI, EDUARDO N.

Examiner

Thai-An N Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_.

### DETAILED ACTION

Claims 1-33 are currently pending.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5 and 11, drawn to methods of generating adult stem cells by implanting at least one micro-organ derived from adult tissue into a mammal in a manner enabling the migration of cells out of said micro-organ, classified in class 424, subclass 93.2, class 435, subclass 325, for example.
- II. Claims 6-10, drawn to methods for inducing stem cell differentiation by co-culturing isolated stem cells with at least one micro-organ, classified in class 435, subclass 325, 373, 375, 377, for example.
- III. Claims 12-17, drawn to methods for inducing stem cell differentiation by culturing isolated stem cell in micro-organ conditioned medium, classified in class 435, subclass 325, 375, 377, 383, 404, for example.
- IV. Claims 18-28, drawn to methods of generating an artificial micro-organ on an acellular three dimensional scaffold, classified in class 435, subclass 395, 325, for example.
- V. Claims 29-33, drawn to methods of isolating adult stem cells comprising culturing at least one micro-organ derived from an adult tissue in a culture and isolating adult stem cells migrating out of the micro-organ, classified in class 435, subclass 325, 383, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I and any of Inventions II-V are mutually exclusive and independent. The methods of generating adult stem cells by implanting at least one micro-organ derived from adult tissue of Invention I are not required for the implementation of the methods for inducing stem cell differentiation by co-culturing

isolated stem cells with at least one micro-organ of Invention II, the methods for inducing stem cell differentiation by culturing isolated stem cell in micro-organ conditioned medium of Invention III, the methods of generating an artificial micro-organ on an acellular three dimensional scaffold of Invention IV, the methods of isolating adult stem cells comprising culturing at least one micro-organ derived from an adult tissue in a culture of Invention V, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol which each require different technical considerations.

Invention II and any of Inventions III-V are mutually exclusive and independent. The methods for inducing stem cell differentiation by co-culturing isolated stem cells with at least one micro-organ of Invention II are not required for the implementation of the methods for inducing stem cell differentiation by culturing isolated stem cell in micro-organ conditioned medium of Invention III, the methods of generating an artificial micro-organ on an acellular three dimensional scaffold of Invention IV, the methods of isolating adult stem cells comprising culturing at least one micro-organ derived from an adult tissue in a culture of Invention V, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol which each require different technical considerations.

Invention III and either of Inventions IV-V are mutually exclusive and independent. The methods for inducing stem cell differentiation by culturing

isolated stem cell in micro-organ conditioned medium of Invention III are not required for the implementation of the methods of generating an artificial micro-organ on an acellular three dimensional scaffold of Invention IV, the methods of isolating adult stem cells comprising culturing at least one micro-organ derived from an adult tissue in a culture of Invention V, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol which each require different technical considerations.

Inventions IV and V are mutually exclusive and independent. The methods of generating an artificial micro-organ on an acellular three dimensional scaffold of Invention IV are not required for the implementation of the methods of isolating adult stem cells comprising culturing at least one micro-organ derived from an adult tissue in a culture of Invention V, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol which each require different technical considerations.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

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